The FDA’s New Position on Dental Implants

Thomas J. Balshi, D.D.S., F.A.C.P.

The FDA’s Dental Products Review Panel’s analysis of the need for standardized scientific and clinical study resulted in new guidelines. It is virtually impossible for a dental professional to select the most suitable form of treatment without solid documentation. The new FDA guidelines will make it possible to reliably prognosticate success or failure for any given implant system.

The field of implants is complex and involves many variables but no more so than most other contemporary medical procedures. A predictable prognosis can be achieved through both rigidly defined clinical procedures and well conducted longitudinal clinical trials. These are implicit in the FDA’s guidelines and the premarket approval (PMA) process.

The FDA’s guidelines will promote equality since every manufacturer can demonstrate the safety and efficacy of their own implants. FDA supervision will reduce the exaggerated claims by the manufacturers concerning success rates and clinical simplicity.

In medicine, the safety of the patient dictates that products are neither safe nor effective until proven to be so. The guidelines call for the completion of 3 years of prospective studies and 2 additional years of scrutiny after continued on page 4

Academy of Crown & Bridge — Scientific Session, Chicago 1989

The UCLA Abutment


The Branemark system was designed to fabricate fixed restorations for edentulous patients. When using the components in the restoration of partially edentulous patients several problems arise. First, adequate interocclusal distance between the abutment cylinder and the opposing occlusion may be lacking. Also, the exposure of the abutment cylinder as it emerges above the gingival crest may be esthetically displeasing, and finally, it may be difficult to develop ideal contours in the definitive restoration with the conventional components. This report describes the use of a newly developed means of using a customized transmucosal abutment in such a way as to connect the dental restoration to fit directly and precisely onto the osseointegrated fixture. Bypassing the titanium abutment and gold palladium cylinder continued on page 5

Considerations in Posterior Glass-Ceramic Restorations


The glass ceramic restoration has been used clinically since 1978. Dicor has optical effects superior to commercially available feldspathic porcelain materials and is generally considered to be a restorative material for anterior teeth. This paper describes the rationale and the use of Dicor for individual complete or partial coverage restorations of posterior teeth.

Glass ceramic restorations have strength that is superior to that of dental feldspathic porcelain. They are susceptible to fracture by excessive tensile or lateral force only if they have deficient material thickness. To ensure strength and eliminate fracture due to function, a preparation depth and/or thickness of 1.2 to 1.5 mm is advocated. The author analyzed 1,077 glass ceramic crowns: 702 placed on posterior teeth and 375 on anterior teeth. continued on page 5

Photostatic Analysis of Stress Transfer to the Supporting Structure by Endodontically Treated Teeth—The Influence of Different Restorative Techniques

David Assif, D.M.D.

Contradictory opinions exist regarding the inclusion of posts in the restoration of endodontically treated teeth. Recent reports indicate that the method of post and core technique may not be as significant as the placement of a full coverage restoration with margins on tooth structure. The influence of different restorative techniques of endodontically treated teeth on the stress transfer to the supporting tooth structure was examined. When a post and core was covered by a complete crown with 2 mm margins on tooth structure and subjected to loading, there was no difference between the two post designs analyzed. It is possible that the complete crown may be the great equalizer, as it tends to change the distribution of forces continued on page 5

A Prefabricated Thompson Dowel Rest Attachment System for Distal Extension Removable Partial Dentures

Ira D. Zinner, D.D.S., M.S.D.

In the treatment planning for restoration of periodontally involved dentitions, a prefabricated Thompson dowel rest semiprecision attachment system for distal extension removable partial dentures deserves consideration. This prefabricated system provides for rotation and therefore stress breaking with controlled movement. Other stress breaking systems provide for rotation without specific control. In addition, the Thompson dowel rest system is the only stress breaker that is intracoronal not extracoronal. The N-L attachment system offers facilitation of laboratory procedures, eliminates the need for utilization of gold for dowels, reduces the size of the rest seats, and aids in the preservation of the integrity of the hard and soft supporting tissues. continued on page 5
Bone Resorption around Fixtures in Edentulous Patients Treated with Mandibular Fixed Tissue-Integrated Prostheses

Lars W. Lindquist, D.D.S.
Birger Rockler, D.D.S.
Gunnar E. Carlsson, D.D.S., Ondond, Dr.

The gradual reduction of edentulous residual alveolar bone supporting complete dentures is a major oral disease entity. Several longitudinal studies have indicated that morphologic changes of denture-bearing regions are inevitable even if they show great individual variation. Changes of the prosthesis support, especially in the mandible, may compromise denture wearing and masticatory functions. The successful replacement of lost natural teeth by tissue integrated dental implants is therefore an exciting improvement in clinical dentistry. Of particular interest is the reaction of the bone after implant therapy. This article analyzes bone resorption around fixtures in association with treatment of the edentulous mandible with a fixed prosthesis on tissue integrated implants. Forty-six patients treated with osseointegration implant method according to Branemark were followed for an observation period of up to 6 years.

Life-long function seems likely for most tissue integrated implants.

The most remarkable finding is the extremely small amount of bone resorption that occurred during the first 6 years after treatment with fixed tissue integrated prostheses in previously edentulous mandibles. The long-term prognosis for osseointegrated fixtures appears to be extremely good. With less than 0.1 mm bone loss per year after the postsurgical period, lifelong function seems likely for most tissue integrated implants.

Oral hygiene was found to be the most important factor associated with marginal bone loss. The reactions in the marginal soft tissues and the microbiota in the perifixture pockets seem to differ from those around natural teeth. The careful instructions in oral hygiene recommended for TIP patients to avoid compromising gingival health seem also to be necessary to minimize the bone loss around the fixtures.

Parafuncional activity such as bruxism, both as reported tooth clenching and recording of occlusal wear on the prosthesis, led to increased bone loss. The correlation between the length of the cantilever extensions and bit force on the one hand and some bone loss values on the other also indicated possible influences of overloading. The multivariate analysis verified that a combination of poor oral hygiene and excessive loading were the factors that best could explain the variation in bone loss.

From a clinical point of view, the most distal fixtures in patients with cantilever prostheses have usually been assumed to be exposed to the most risk. This does not appear to be so with respect to bone loss, according to the present results.


Single-Tooth Rehabilitation Using Osseointegration. A Modified Surgical and Prosthodontic Approach

Lars-Olof Oreinell, D.D.S.
Jan M. Hirsch, D.D.S., Ph.D.
Ingvar Ericsson, D.D.S., Ph.D.
Per-Ingevar Branemark, M.D., Ph.D.

Loss of teeth may cause severe disturbances of a patient’s masticatory function, comfort, and psychological nature. For esthetic and functional reasons, most people want to replace even a single lost tooth. Replacement of a single missing tooth with an osseointegrated fixture as an abutment for an individual crown has previously only been used in a limited number of cases. The reasons for this have mainly been technical and esthetic problems. In order to improve the esthetic possibilities, shorten the treatment period, and simplify the procedure for replacing a single lost tooth using osseointegration, a modified surgical and prosthetic procedure is implemented.

This paper describes a modified procedure for the immediate replacement of a single tooth. In principle, two modifications of the fixture are introduced: first, the hexagonal part is extended (0.7 to 1.2 mm), simplifying the abutment connection; second, the conical part varies in diameter (3.0 to 5.0 mm). The conical shape of the superior part of the fixture will optimize the contact area between the bone tissue and the fixture. Despite this conical shape gaps may occur between the bone tissue and the titanium surface. In such situations, however, spongy bone is grafted from adjacent areas and properly packed into this space, ensuring intimate contact between the bone and the titanium surface and thus eventually enhancing the possibilities for osseointegration. Furthermore, functional loads applied to such a conically shaped fixture will be favorably distributed to the supporting alveolar bone.

The part of the abutment fitting the fixture is inversely conical in relation to the fixture and varies in length between 5 and 9 mm, which makes it possible to place the conical part of the abutment subgingivally. Supragingivally the hexagonal part of the abutment is exposed and serves as a post for the artificial crown to be installed. The subgingival part is conically shaped in order to facilitate a favorable adaptation of the gingival tissues to the abutment as well as to obtain a perfect fitting of the subgingival part of the crown (Figure 1). The use of a cemented crown facilitates adjustments and corrections such as those created by color changes or wear, without disturbing the dynamic equilibrium of the mucoperiosteal interface.

Schematic drawing illustrating single-tooth components in situ.

Photograph illustrating position analysis of the fixture to be installed.

Because the subgingivally located conical part of the abutment varies between 5 and 9 mm in length, the probing (“pocket”) depth also may vary between 5 and 9 mm. Clinical studies analyzing the composition of the plaque present in pockets surrounding titanium abutments have clearly demonstrated a flora representing a healthy periodontal situation even when the pocket depth has been somewhat deepened. Providing that the patient exhibits a high standard of oral hygiene, the risk for loss of supporting alveolar bone around such titanium abutments is low even when the pocket depth is increased. When a single missing tooth is replaced using standard fixtures and continued on page 3
abutments, a very common problem is loosening of the center screw, which leads to a loose abutment and rotation of the crown. Such complications can be avoided by using the modified titanium component presented in this report. Further, the artificial crown is cemented on the abutment, which increases the possibility of good esthetics and further decreases the risk that the crown will become loose.


Comparative Analysis of 100 Consecutively Placed Core-Vent Implants to 100 Consecutively Placed Biotics (Branemark) Implants

P. K. Moy

To date, many articles have been published stating the success and/or failure rates of a particular endosseous implant system, based on an individual clinician's experience. The purpose of this analysis was to compare the success rate of the two systems, based on a single practitioner's experience. The method included the same surgical technique, experience and post operative care for all patients, assuring minimal variations and discrepancies. Failures were defined and identified according to jaw position, timing of failure and treatment outcome. Complications associated with the two systems were also described.

Included in the study and analyzed in the report data were 101 Branemark fixtures in 31 patients and 100 Core-Vent Implants in 32 patients.

The definition for absolute failures is the fixtures or implants that were removed. The author categorized potential or progressing failures which would cover looseness or mobility of more than +3 mm, soft tissue dehiscence, inflammation around the implant, and osseous pocketing of more than 5 mm radiographic lucency or chronic infection. The results: the Core-Vents were followed for a maximum of 3 years, minimum of 1 year. The Branemark fixtures were followed for a maximum of 2 years, 3 months, a minimum of 1 year.

The Branemark results in the maxilla had 92% success and included 2 failures out of 26; in the mandible, 99% success with one failure out of 75. The combined success rate was 97%. Considering the potential or progressing complications, in the maxilla, there were none and all implants were solid. In the mandible there were 2 complications: one fixture was fractured; however, the prosthodontist did restore it, and the other had threads exposed. Evaluating this data, one would project a success rate of 92% in the maxilla and 96% in the mandible with a combined total of 95%.

Examining the Core-Vent implants, the facts were as follows: in the maxilla, 5 out of 31 failed (84% success); in the mandible, 9 out of 69 failed (87% success) with a combined success of 86%. In the category of potential or progressing complications, the maxilla had 5. Of those, 6 had +3 mobility or greater with radiolucencies around the Core-Vent implants. Two had pocket depths of greater than 5 mm.

In the mandible, 13 out of 69 Core-Vent implants presented problems or complications. Three had +3 mobility and radiolucency around the entire implant, six had pocket depths of more than 5 mm, and four had chronic infections around the loaded implant. Considering this data, a 79% success rate was tabulated with regard to potential or progressive complications.

With all Core-Vent implant data analyzed in this study the projected failure rate in the maxilla was 58%, and 68% in the mandible, with a combined success rate of 65%.

Dr. Moy concluded that the Branemark system provided a more consistent clinical result with fewer complications. The present Core-Vent data must be viewed cautiously in light of the involvement with progressive complications which may result in future implant failures. It was noted that all Core-Vents were inserted prior to the company's introduction of the new twist or spindle drills as well as their prepackaged system.

* Presented at the Second International Congress of Preprosthetic Surgery, May 1987, Palm Springs, CA.

Osseointegrated Implants (Tubingen, IMZ, Branemark) — Management Concept and Experiences

G. Watzek, M. Matejka, W. Lill, G. Mailath, P. Matzka and H. Plenk

An implantological concept based on osseointegrated implants (Tubingen implant, intramobile cylindrical implant (IMZ), Branemark implant) in service for 5 years and the 10 factors predictive of implant success are reviewed. The original concept, which almost always included preprosthetic surgery, was continually reevaluated clinically (periodontal examinations, Perioste test measurements, denture follow-ups, X-ray studies, etc.). Associated basic research and animal experiments suggested several improvements. Under optimal conditions, near-physiologic implant integration appears to be realistic prospect. But a great many conditions and factors must be met to produce and maintain implant integration. Still, implants have already acquired a place in the management of patients with edentulous mandibles. They meet the anatomical requirements and can be offered to suitable candidates as a true alternative to conventional full dentures.


Cost Effectiveness: A Bargaining Chip? (an Editorial)


Because of the many elective facets of dental restorative care, payors more and more look to the cost effectiveness of procedures and material systems in making support decisions. High quality care is not necessarily the most expensive, furthermore, it can often be less expensive. While a contract provider may offer lower prices up front, there is no guarantee that lower costs will prevail long term.

Preventive dentistry is becoming more attractive because of its cost effectiveness. If predictable long-term solutions to common problems are available, even though more costly initially, their use may be financially more cost effective in the long run.

Perhaps more important than the pecuniary cost benefit is the biologic cost effectiveness of predictable implant therapy. As integrated implants remain in appropriate function, they in fact encourage bone retention and actually contribute to bone conservation.

Mismangement of the prosthodontic phase of treatment can adversely affect the most reliable of implant modalities. Misuse or misapplication puts the patient at risk.

When well-designed and fabricated prostheses are placed on predictable implant support in the mouths of caring patients, the result can be long lasting, provide comfort, and protect "that which remains" of the biologic foundation.

What better value for the cost can one ask?
Can We Talk?
Daniel M. Laskin

The oral and maxillofacial surgeon is at a considerable disadvantage when it comes to having the time necessary to build a firm relationship with his patients. Thus, it becomes necessary to develop an approach to gaining the patient's confidence and cooperation that can be accomplished quickly and effectively.

The physical surroundings of the office and the courtesy and attentiveness of the staff are very important in setting the stage, as are the doctor's dress and demeanor, but most important is the manner in which he speaks to patients. Proper conversation is the key to making the first impression a good one. It is essential in communicating with the patient to be friendly, to be informative and to show concern. Telling a patient exactly what to expect can go a long way toward improving cooperation and reducing complaints.

Our conversations with patients should also extend beyond the initial encounter and into the operative period. Calm reassurance can serve as vocal sedation for patients who are not premedicated and reduce the need for additional medication in those who are pharmacologically sedated. An honest explanation of what is occurring also gains the patient's confidence and leads to better cooperation.

Just as we have to be careful about what we say to the patient during the operation, we must be careful about what is said by others who are present. We also have to be cautious about our choice of words when requesting instruments. "Hand me a drill" or "get me a mallet and a chisel" can be replaced by less threatening words like "handpiece" or "osteotome."

Conversations in the operative area often involve the ancillary personnel as well as the patient and these too must be carefully monitored. Patients sometimes inaccurately assume that what was said referred to them.

Developing a rapport with our patients through proper conversation has many obvious advantages, not the least of which is a reduction in potential litigation. Patients are less likely to challenge the competence of surgeons they like, trust, and respect. Thus, appropriate communication as part of good patient management is also part of good risk management. It has often been said that talk is cheap. Perhaps it is better to remember that a lack of conversation can also be expensive.


Electronics in the Body Shop
Marshall Ledger

Should people who need a biomedical device subject themselves to experimental science? Take, for instance, the cochlear implant, which simulates acoustic signals and restores sounds and even an understanding of speech to some otherwise deaf people. Frank Bowe, a 1969 graduate of Western Maryland College who chaired the United States Commission on Education of the Deaf, does not now recommend this type of implantation.

Bowe is deaf. He points out that the cochlea lies dangerously near facial nerves that could be severed by miscalculated surgery—a penalty too stiff for the current status of cochlear-implant technology.

But assume that a cochlear implant involved no risk. Patients would still face the recurring health-care question of access and cost. Currently a cochlear device, including surgery, costs about $20,000, and physicians cannot tell how much a patient will benefit from it before the implant.

Will insurance pay for something so uncertain? Some devices enhance the quality of life without obviously changing the productivity of the recipients. Will insurance companies be eager to cover costs in such cases, even though the technology could cut the cost of full-time care, not to mention both the financial and emotional drains on the families?

In the United States, health-care costs already consume some 11% of the gross national product. New devices bring new dilemmas, if only over the cost. For example, an implantable defibrillator can sense whether blood is being pumped to the heart and within seconds send an electric shock to restart the heartbeat.

Long-term care for a brain-damaged patient is extremely expensive. But the implantable defibrillator costs about $15,000; tests, surgery, and recovery might run another $20,000.

Alfred Potvin devoted 17 years to university teaching before working on biomedical products. When his students questioned cost, distribution, and ethics, he let them respond to each other's points. "Invariably," he said, "I'd find that you get into a controversy that no one has an answer to"—which is about where we are in the real world.


FDA's New Position continued from page 1

the product has been allowed onto the market. I question if this time period is long enough to sort out all the deleterious systems.

An implant restoration must be considered to be a long-term solution for the patient. Following the three years of prospective studies the implant system should be evaluated for an additional five more years. It is conceivable that mechanical stability alone, without any osseointegration at all, could last for more than five years in some cases. But hardly more than ten.

The long-term predictability of implant treatment depends upon implant material, design, surface structure, condition of the bone, surgical technique, prosthetic design and patient hygiene.

continued on page 5
FDA's New Position continued from page 4

The FDA's intention is to apply the guidelines to the abutment portion of an implant that is separate from the portion that is inserted into the bone. Material compatibility and the structural reliability between the abutment and fixture and its relationship to the soft tissue surrounding the abutment all play an important role in implant stability and the health of the bone and mucosal tissue.

Galvanic reactions, metal pitting and corrosion may be caused by dissimilar materials. A poor fit between the abutment and gingiva or abutment and the fixture can increase the risk of soft tissue inflammation and compromise the functional performance and mechanical properties of the implant.

The real value of the FDA's guidelines is to assure that patients are treated with implant systems that provide predictable success and work for a long time. For the patient, a failure is a failure, whatever the reason. In the near future we will probably see implants currently available falling into two groups: those that could not afford or weren't willing to commit themselves to expensive research; or implants that were just not good enough to undergo scientific scrutiny. The surviving systems will be the implants and methodologies and corporate philosophy willing to make a long term commitment to basic science, engineering and clinical research and the extensive documentation required by the FDA.

In an era occupied with "de-regulations" our profession should applaud and value the importance of the FDA's new position on dental implants. These guidelines and regulations, although demanding, will help protect the implant manufacturer, the practitioner and most importantly the patients we treat.

UCLA Abutment continued from page 1

with the "UCLA" abutment provides added space permitting more ideal dental restorations.

The author reports on 17 patients with 45 implants over a one year period restored with the "UCLA" abutment. Neither excessive bone loss, fracture of implant components or restorations, nor clinical signs of electrogalvanism or electrolytic corrosion have been noted. All patients remain completely asymptomatic. Numerous periodontal and restorative measurement parameters are currently being used to assess its long term clinical applicability.

The "UCLA" abutment initially has proven to be successful where inadequate interocclusal space exists, and greatly improves the esthetic results over those achievable with the conventional implant components. In addition, the contours of the restoration itself can be improved. By eliminating the transmucosal titanium abutment, porcelain surfaces can be made to emerge through the gingival crest providing a much improved esthetic result.


Photoelastic Analysis continued from page 1

to the root and post and core complex, and the post characteristics become insignificant.

The report showed no recognizable reduction of forces in the CEJ area due to post placement. Also the high concentration of forces at the apex did not bear witness to the claimed even distribution of forces along the length of the root. Thus it should be taken into consideration that perhaps the current concept of a metal post does not meet all the special needs of an endodontically treated tooth.

It seems that a post does not protect the tooth. This paper concluded that when there is sufficient coronal structure to retain a crown a post and core should be avoided. Preparation of the tooth to receive a post results in an additional loss of dentin, and it must not be forgotten that economy in dentin loss is cardinal. When there is a need to use a post to retain a core the thinnest tapered-end post is recommended.


Considerations continued from page 1

The failure (breakage) rate for both has been less than 4%. The majority (44%) of these failures occurred in early units that were made in research prototype equipment. It has not been observed that an intrasurface ceramic fracture, such as a broken cusp, has occurred.

Advantages: Advantages of the glass ceramic unit include the smooth finish of the surface, decreased plaque retention, the fine marginal fit, and wear similar to human enamel. If the colorants have been removed, a natural translucent edge occurs which does not detract from the esthetics of the restoration.

Luting: The newer polyurethane luting agents that are light activated and designed for Dicor possess superior properties in tensile and compressive strengths. This is most significant because ceramics break due to tooth movement and stresses that focus at the cement-ceramic seal. The light activated luting agents are strong enough so that the stresses are transferred away from the seal and dissipated in the body of the tooth itself.

Plaque is the key etiologic agent to both caries and periodontal disease. Plaque does not adhere significantly to the Dicor surface with or without colorants.

Research has shown that bacterial growth found on the Dicor surface was primarily a gram-positive flora and is seen seven times less than that found on the natural tooth surface.

Dicor restorations have been used successfully in complete or partial coverage on posterior teeth. Its use in the dental practice can be simple, accurate, predictable and consistent.


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Thompson Dowell continued from page 1

The prefabricated dowel rest-mandrel is composed of a cobalt chrome alloy. It is 1.5 mm wide buccolingually. The well is 2 mm deep and 1 mm wide, the tapering recess is 8 mm high, while the shelf is 1 mm wide. The taper of the rest-mandrel is 1½ degrees. A vertical shaft is attached to the superior aspect of the tapering recess to allow it to be held in the dental cast surveyor to form a rest seat in the wax pattern of the planned abutment casting. The buccolingual width of 1.5 mm allows the rest-mandrel to be placed into anterior teeth and premolars without overcontouring, and thereby maintain normal crown contour. The rest-mandrel has a tang that is shaped to allow the use of a detachable horizontal mandrel. With this tool...
the technician is able to create the desired parallelism between the counterpart rest seats in the abutment crowns both horizontally and vertically. The tang permits retention into the acrylic resin of the denture base or for direct casting to the metal of the removable partial denture framework. The cobalt-chrome alloy is used for the framework interlock with the tang without milling the rest and no soldering procedure is required. The prefabricated rest-mandrel provides for a simplified means of replacement, when it is needed. The replaced rest may be attached with autopolymerizing acrylic resin or soldered to the existing removable partial denture metal framework.

A cobalt-chrome alloy prefabricated Thompson dowel rest system has been introduced which eliminates: 1) the use of gold for dowels, 2) individual casting of the rest, 3) soldering of the rest to the removable partial denture framework, and thus results in a reduced expense for construction, as well as a simplified means of replacement when necessary.


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   Institute for Applied Biotechnology
   Gothenburg, Sweden
   
   **Topic:** Anatomy of Osseointegration in Optimal Oral Rehabilitation

2. **William R. Laney, D.M.D., M.S.**
   Mayo Clinic, Rochester, Minnesota, USA
   
   **Topics:** Tissue Integrated Prosthesis
   1. Diagnosis and Treatment Planning
   2. Complex Treatment Situations
   3. Results & Complications

3. **Torsten Jemt, D.D.S., Ph.D.**
   Branemark Clinic, Gothenburg, Sweden
   
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   University of Umeå, Sweden
   
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   2. Partial
   3. Esthetics in Complex Treatment Situations
   4. Material Development

6. **Bo Rangert, Ph.D.**
   Nobelpharma AB, Denmark
   
   **Topic:** Forces and Moments on Branemark Implants in Various Clinical Applications

For additional information, call IFFE: 215-643-5881

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Instructions for the Production of Radiographs To Be Examined by Computer-Aided Image Analysis

*Lars Hollender, Birger Rockler and Karl-Gustav Strid*

In order to assess the anchorage function of osseointegrated titanium implants, radiographs of implant patients are analyzed by means of a computer-based system at The Institute for Applied Biotechnology in Gothenburg. Features extractable from the radiographs comprise marginal bone height, bone density, and bone architecture. From these it should be possible to determine the quality of osseointegration and to give a prognosis as to the long-term outcome of individual fixtures. It is necessary, then, to provide a scheme for the production of standardized radiographs to be submitted to Gothenburg for evaluation.

It is important that the different radiographs pertaining to any individual patient be produced by a standardized procedure, so that radiographs obtained on different occasions may be readily compared. Once local radiographic routines have been established, it is important that they be strictly adhered to.

The radiographs intended for computer-aided analysis should be mounted in suitable frames, marked with the patient’s name and identity number, the reference number of the jaw, the date of examination and the reference designations of the respective fixtures. The x-ray-tube voltage should be indicated on the frames.